

REMARKS

Applicants would like to thank the Examiner for issuing a non-final second office action in this matter. Applicants would also like to thank the Examiner for withdrawing the objection to claims 140, 220, and 360, as well as withdrawing the rejection of claims 29-34, 81, 83, 85, 86, 94, 100, 125, 126, 134, 201, 205, 206, 214, 345, 346, and 354 under 35 U.S.C. 112, and the rejection of claims 29 and 34 under 35 U.S.C. 102.

In an Office Action dated November 30, 2004, claims 29-34, 81-99, 121-139, and 341-359 were rejected, and claims 201-219 were withdrawn as being drawn to a non-elected invention. Claims 201-219 are now Canceled, as are claims 90, 130, and 350. By this amendment, claims 29-31, 81-83, 85, 87-91, 95, 98, 99, 121-123, 125, 127-131, 135, 138, 139, 341-343, 345, 347-351, 355, 358, and 359 have been amended. Claims 381-398 have been added. Claims 29-34, 81-99, 121-139, 341-359, and 381-398 are now pending. Applicants request reconsideration of the pending claims in view of the present amendment and following remarks.

Telephonic Interview

Due to the complexities of the issues in the pending Office Action, the applicants respectfully request that the Examiner contact the undersigned to conduct a telephonic interview regarding this response and the pending Office Action.

Elections/Restrictions

The Examiner has noted that Claims 34 and 201-219 encompass non-elected subject matter: corn plants or seeds directed to varieties *mop1-1* and *mop3-1*. Applicants agree that *mop3-1* is a non-elected subject and have amended claim 34 to reflect this. However with respect to *mop1-1*, Applicants respectfully disagree. New Claims 381-398 directed to *mop1-1*, are clearly part of Group I identified by the Examiner in the restriction requirement mailed 1/30/04, along with claims 29-34, 81-100, 121-140 and 341-360. This Group was elected by the Applicants in the response to the restriction requirement mailed 3/1/04. The group was drawn to "...a mutant corn plant

comprising one or more mutations wherein said one or more mutations cause an increase in expression of a transgene...” *mop1-1* falls into this category since this mutation has been shown to increase the expression of a transgene. By way of example, applicants direct the attention of the Examiner to paragraph 324 of the specification, which discusses the four mutations that relieve transgene silencing (i.e., increase expression of a transgene). *mop1-1* is clearly included in that group of four mutations.

Since *mop1-1* is within the subject matter of the elected invention, Applicants request reconsideration and allowance of claim 34, as well as claims 201-219. However, in order to expedite examination, claims 201-219 have been Canceled and resubmitted as New claims 381-399. In view of these remarks, Applicants request that the examiner withdraw the objection to claim 24 and not object to New claims 381-399.

Specification

Applicants acknowledge the error regarding figures 6 and 24. Substitute figures were already submitted in the Response to Notice to File Corrected Application papers dated January 29, 2002. No substitute figures are now needed, and the brief description of figure 24 has been amended to address the labels in the substitute figures already submitted.

The specification has been amended to remove the hyperlinks and correct the address of the ATCC. Line 3 of paragraph 00173 of the specification has also been amended to replace the recitation “effective” with “enforceable”. Applicants respectfully request that the Examiner withdraw the objection to the specification.

Claim Objections

The Examiner has objected to claims 87, 90, 127, 130, 207, 210, 347, and 350 under 37 CFR 1.75(c) for failing to limit the subject matter of a previous claim. Claims 87, 127 and 347 have been amended to be independent claims. Claims 90, 130, and 350 have been Canceled.

Applicants respectfully request that the Examiner withdraw the pending rejections to claims 87, 127, 347, and allow New claim 387, which replaces Canceled claim 207.

Claim Rejections – 35 USC § 112, second paragraph

The Examiner has rejected claims 91, 131, and 351, as well as 29-34, 83, 85, 87-90, 91-93, 95-99, 125, 127-134, 138-139, 212-213, 345, 347-354, 358, and 359 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

The Examiner has rejected claims 91, 131, and 351 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The Examiner has asserted that the recitation “can regenerate” is not clear. Applicants respectfully disagree with the Examiner’s grounds for rejection. The recitation “can regenerate” describes an easily measurable phenomenon. The Examiner suggests replacing the recitation “can regenerate” with “regenerates”. Applicants point out that this would essentially add an active step to change a composition of matter claim in a plant to a method claim. This is not the Applicants’ intent, and therefore the applicant respectfully requests reconsideration of these rejections against claims 91, 131 and 351.

The Examiner has rejected claims 29-31, 87, 90, 95, 98, 99, 127-130, 347, 349, and 350 as being indefinite due to the recitation “the transgene is hypomethylated”. Applicants respectfully disagree with the Examiner’s grounds for rejection. The Examiner states that the claim does not indicate whether the transgene is hypomethylated in the non-transgenic corn plant. The methylation state in the non-transgenic plant is the control level of methylation. The transgene in the mutant plant is hypomethylated as compared to the methylation state of the transgene in a non-mutant transgenic plant. Assessing the degree of methylation of the transgene in mutant and non-mutant plants would be a simple experiment well known to those skilled in the art, for example Southern Blotting after digestion with a methylation-state specific restriction enzyme (see paragraph 192). To clarify this point, claim 29 has been amended to include the recitation “...the transgene is

hypomethylated compared to the methylation state of the transgene in a non-mutant transgenic corn plant...” Support for this amendment already exists in the specification, namely in above-mentioned paragraph 192 entitled “Analysis of Global DNA Methylation Levels” as well as paragraph 218 entitled “Mop1-1 Does Not Affect Global Methylation Levels”. Independent claims 81, 87, 95, 121, 127, 135, 341, 347 and 355 have also been amended to include this description. By these amendments, dependent claims 30, 31, 98, 99, 128, 129, and 349 also contain the description of hypomethylation. Claims 90, 130, and 350 have been Canceled. Applicants therefore request withdraw of the rejection of claims 29-31, 87, 90, 95, 98, 99, 127-130, 347, 349, and 350.

The Examiner has rejected claims 30 and 31 as being indefinite due to the recitation “Mutant, transgenic seed”. The Examiner states that the claims do not make clear whether the mutation is the same as that of claim 29, or some other mutation. The mutation referred to in claims 30 and 31 is the same mutation as that of claim 29. The mutation referred to here is a mutation which causes the hypomethylation and increase in expression of the transgene in claims 29, 30 and 31. These claims have been amended to clarify this issue. Applicants respectfully request that the Examiner withdraw the rejection of claims 30 and 31.

The Examiner has rejected claims 83 and 87-90 as well as claims 98 and 99, 127-130, and 347-350 as being indefinite due to the recitation “Mutant, transgenic seed” or “Progeny mutant seed”. In claims 83 and 87-90 as well as 98 and 99, the Examiner feels it is unclear whether the mutation is the same as that in the corn seed of claim 81 or 82, *rmr2-1*. The same mutation is referred to in claims 81 through 99, the *rmr2-1* mutation. Claims 121 through 139 all have the *Mop2-1* mutation. Claims 341 through 359 all have the *rmr1-1* mutation. The term “mutant” in all of these claims refers to the mutation which causes the hypomethylation and consequent increase in expression of a transgene, namely the mutations discussed in the application: *rmr2-1*, *Mop2-1* and *rmr1-1*. We have amended claims 83, 87-90, 98, 99, 127-130, and 347-350 as well as corresponding claims 82, 122, 123, 342, and 343 and also claims 81, 85, 95, 121, 125, 135, 341, 345, and 355 to reflect this. Applicants respectfully request that the Examiner withdraw the rejection of claims 83, 87-90, 98, 99, 127-130, and 347-350.

The Examiner has rejected claims 85, 125, and 345 as being indefinite due to the recitation “genotypic characteristics”. Applicants respectfully disagree with the Examiner’s grounds for rejection. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to replace the recitation with “genotype”. Applicants respectfully request that the Examiner withdraw the rejection of claims 85, 125, and 345.

The Examiner has rejected claims 91, 130, and 351 as being indefinite due to the term “mutant” in the recitation, “a tissue culture of regenerable mutant cells of corn plant genotypically designated *rmr2-1*”. The Examiner feels it is unclear whether the mutation of the cells of the tissue culture is the same mutation, or some other mutation. The mutation is the same, and we have amended claims 91 and 351 to reflect this, as claim 130 was amended above to clarify this same issue. We have also amended claim 131 to clarify this point. Applicants respectfully request that the Examiner withdraw the rejection of claims 91, 130 and 351.

The Examiner has rejected claims 131 and 351 as being indefinite due to the recitation “mutant, transgenic cells of a corn plant designated *Mop2-1* (or *rmr1-1*)”. The Examiner states that corn plants *Mop2-1* and *rmr1-1* are not transgenic. While the Original plants themselves are not transgenic, the claim was meant to describe these plants after the introduction of a transgene. The mutations *Mop2-1* and *rmr1-1* cause the increased expression of an introduced transgene. Claims 131 and 351 have been amended to clarify this point, as well as corresponding claim 91. Applicants respectfully request that the Examiner withdraw the rejection of claims 131 and 351.

The Examiner has rejected claims 138-139 as being unclear whether the mutation in the claimed hybrid seed and plant is the same as *Mop 2-1*. Claims 121-139 all refer to the *Mop2-1* mutation, therefore the mutation is the same, and the claims have been amended to reflect this. Applicants respectfully request that the Examiner withdraw the rejection of claims 138-139.

The Examiner has rejected claim 345 as being unclear as to why the term “transgenic” is used to describe the corn plant of claim 342 when this plant is not transgenic. Claim 345 is to the mutant corn plant (which has the genotypic characteristics of the corn plant of claim 342) with the

addition of a transgene. The *rmr1-1* mutation will cause the hypomethylation and increased expression of a transgene. The claim has been amended to clarify this issue, as well as the corresponding claims 85 and 125. Applicants respectfully request that the Examiner withdraw the rejection of claim 345.

The Examiner has rejected claim 348 as being unclear because it is directed to a mutant, transgenic corn plant produced from the seed of claim 348, but the seed of claim 348 is not transgenic. Claim has been amended to include a transgene. Applicants respectfully request that the Examiner withdraw the rejection of claim 348.

The Examiner has rejected claim 350 as being as being indefinite due to the recitation “a transgene”, as to whether it refers to the same transgene as that mentioned in claim 349. Claim 350 has been Canceled; therefore, applicants respectfully request that the Examiner withdraw the rejection of claim 350.

The Examiner has rejected claims 358-359 as being unclear. Applicants have amended the pending claims, to show that the mutation in both the claimed hybrid seed and plant is *rmr1-1*. Applicants respectfully request that the Examiner withdraw the rejection of claims 358-359.

In light of the above comments and amendments to the claims, the Applicants respectfully request that the Examiner withdraw the pending rejections to claims 29-34, 83, 85, 87-90, 91-93, 95-99, 125, 127-134, 138-139, 212-213, 345, 347-354, 358, and 359.

Claim Rejections – 35 USC § 112, first paragraph, enablement

The Examiner has rejected claims 34, 81-99, 121-139, and 341-359 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants thank the Examiner for pointing out the incorrect mailing address for the ATCC, and have amended the specification to correct this mistake.

The Examiner has rejected claims 29-34, 87, 90, 95-99, 127-134, 345, 347, and 349-354 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement because the specification does not reasonably provide enablement for any other mutant, transgenic corn plants, seeds or tissue cultures, or for the increase in expression of all types of transgenes.

The Examiner also states that claim 29 encompasses corn plants that comprise any type of mutation, and that no guidance is provided in the specification as to how one skilled in the art would make any other type of mutant, transgenic corn plant, or what other types of mutations have such an effect on transgene methylation and expression. Applicants respectfully disagree, claim 29 is to a composition of matter which is a mutant corn plant comprising a transgene which is hypomethylated compared to the transgene in a non-mutant corn plant. The hypomethylation is a clear structural limitation that is fully enabled. Applicants have more than met the enablement requirement set forth in MPEP 2164.01(b), which states: "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." This application provides not one but four methods for making and using the claimed invention, and as such Applicants feel the enablement requirement has been met. The term "hypomethylated" is a term of comparison well known to those of skill in the art. It is a term which requires comparison to a base line state of methylation. That is why the claim includes the term mutant. The transgene in the mutant plants as compared to non-mutant plants is hypomethylated. Furthermore, even if the applicants needed to enable more than the four mutations disclosed to support the enablement, applicants refer the Examiner to paragraph 292 of the specification, which describes a genetic screen for mutations of the invention. The specification thus provides clear instructions for one of skill in the art to isolate mutations which affect transgene methylation and expression. Thus the applicants have fully enabled the scope of claim 29.

As for the transgenes which can be utilized, the applicants have clearly enabled support for use of other transgenes in the presently claimed invention. The Examiner claims that all of the examples in the specification involved the use of one type of transgenic coding region, B-I. The B-I transgene was used to test the specific mutations described in the specification, and is not meant to

limit the invention to that one transgene. Even though only one transgene was used, it was combined with two different promoters (see paragraph 323), suggesting that the effects seen were not specific to the construct used. Applicants would like to refer the Examiner to paragraph 195, line 19 of the specification, where it is stated that "...*mop1-1* is not specific to B' but also affects the paramutant *PI'* allele." Applicants would furthermore like to direct the Examiner's attention to paragraph 249, line 11 of the specification, where it is stated that "*mop1-1* mutation reverses previously established methylation of *Mu1* elements." These examples in the specification show that the mutations of the invention can affect other coding regions besides the B-I transgenic coding region. These examples are not meant to limit the invention, which is meant to apply to any transgene which can be expressed in plants, not to be specific to a set of transgenes. The mutations taught by the applicants function by a general mechanism of hypomethylation that one of skill in the art would expect to function generally with all transgenes. See Example 2 starting on paragraph 230 of the specification.

The Examiner has not met the burden to establish a *prima facie* case of non-enablement given that the Examiner has not cited to any support for the proposition that applicants have not enabled *hypomethylation* of all transgenes. The Examiner cites to Chandler et al. (Nature Rev. Genet., 2004, Vol. 5, pages 532-544) teaching that not every transgene tested was reactivated as evidence supporting the lack of enablement rejection. However, the Examiner has read into the claims an element that does not appear in the claims, specifically removal of *all* silencing. As the Examiner notes in Chandler et al., there are multiple forms of silencing such as hypermethylation, insertion of transgenes near repressor elements, etc. The present invention only addresses one form of silencing, a specific form that leads to hypermethylation. The presently claimed invention is clearly intended to address only one form of silencing – hypermethylation – which is why the claims recite that the transgene is hypomethylated. Thus, the applicants have enabled the scope of the claims.

In light of the above comments and amendments to the specification, the Applicants respectfully request that the Examiner withdraw the enablement rejections of claims 29-34, 81-99, 121-139, and 341-359.

Claim Rejections – 35 USC § 112, first paragraph, written description

The Examiner has rejected claims 29-34, 81-99, 121-139, and 341-359 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Regarding claims 29-34, Applicants have met the written description requirement. The claims are to mutant plants, seeds, cells, *etc.* which contain a transgene which is hypomethylated as compared to the methylation state of the same transgene in a non-mutant plant. The mutation itself is not irrelevant to the claimed invention; rather the term “mutant” is being used to distinguish from “non-mutant” plants. This comparison is necessary to establish the baseline against which the decrease in the methylation and expression of the transgene is measured. Examples of mutations which produce this phenotype were discussed in the specification; however these examples do not limit the invention to these specific mutations. Even if additional mutants were necessary, a screen could be done to identify mutations which cause hypomethylation and increased expression of a transgene, as such the specification (please see paragraph 292) provides clear instructions for performing such a screen and analyzing the resulting mutations. Claims 29-31 have been amended to hopefully clarify the situation. Applicants respectfully request that the Examiner withdraw the written description rejection of claims 29-34.

Regarding claims 81-99, 121-139, and 341-359, the Applicants thank the Examiner for pointing out the incorrect mailing address for the ATCC, and have amended the specification to correct this mistake. Line 3 of paragraph 00173 of the specification has also been amended to replace the recitation “effective” with “enforceable”. The seeds were tested by the ATCC at the time of deposit and found to be viable. The specification has been amended in paragraph 173 to add the statement that access to the invention will be afforded to the Commissioner upon request and that the seeds were tested by the ATCC upon deposit and found to be viable, thus meeting the remaining requirements cited by the Examiner. Applicants therefore respectfully request that the Examiner withdraw the written description rejection of claims 81-99, 121-139 and 341-359.

Regarding claims 30 and 31, the claims have been amended to remove the recitation “mutant.” Applicants respectfully request that the Examiner withdraw the written description requirement of claim 30 and 31.

Regarding the hybrids that are descendants from claimed varieties deposited with the ATCC, these claims have been amended to make clear that the mutations in the hybrid are the same as the parent plant. Claims 95, 135 and 355 have been amended.

In light of the above comments and amendments to the claims and specification, the Applicants respectfully request that the Examiner withdraw the pending rejections to claims 29-34, 81-99, 121-139, and 341-359, and allow New claims 381-399.

Claim Rejections – 35 USC § 102(a)

The Examiner has rejected claims 341-346, and 354 under 35 U.S.C. 102(a) as being anticipated by Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145).

Claims 341-344 and 346 have been amended to include a transgene, which is not included in Chandler et al, as described below. For claims 345 and 354, they are meant to describe corn plant *rmr1-1* with the addition of a transgene, which makes them different from the plant described in Chandler et al. Claims 345 and 351 have been amended to reflect this point, as well as corresponding claims 85, 125, 91, and 131. In order to anticipate a claimed invention, a reference must teach every element of the claimed invention. Chandler et al., do not teach a corn plant with a transgene as is presently claimed, so Chandler et al. fail to anticipate the presently claimed invention.

In light of the above comments and amendments to the claims, the Applicants respectfully request that the Examiner withdraw the pending rejections to claims 341-346, and 354.

Claim Rejections – 35 USC § 103(a)

The Examiner has rejected claims 341-346, 348, and 351-359 under 35 U.S.C. 103(a) as being unpatentable over Chandler et al. (Plant Mol. Biol., June 2000, Vol. 43, pages 121-145). The Examiner feels it would have been obvious for one of skill in the art to produce tissue cultures of regenerable cells of the mutant plants of Chandler et al.

Claims 341-344, 346 and 348 have been amended to include a transgene, which is not included in Chandler et al, as described below. In addition, claims 345 and 351-359 are drawn to a plant designated *rmr1-1* and also comprising a transgene, which makes them different from the plants described in Chandler et al. Claim 355 has been amended to reflect this, as well as corresponding claim 135.

Applicants submit that after entry of these amendments, a *prima facie* case for obviousness cannot be established, and therefore we request the removal of the rejection. A *prima facie* case of obviousness must meet three criteria: 1) the references must teach or suggest all claim limitations, 2) a suggestion or motivation to modify reference teachings, and 3) one of skill in the art must have a reasonable expectation of success in making the modification or combining the references.

The first criterion, teaching or suggesting all elements, is not met in the cited reference. Chandler et al. do not teach or suggest addition of a transgene to these plants as is presently claimed.

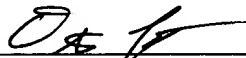
Applicants therefore respectfully request that the Examiner withdraw the obviousness rejection of claims 341-346, 348, and 351-359.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **416272061200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 30, 2005

Respectfully submitted,

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